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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S. W.
Washington, DC 20460

Attn: TSCA Section 8(e) Coordinator (CAP Agreement)

Re: EPA ID No. 8ECAP-0009

Dear Sir or Madam:

BP Chemicals, Inc. submits the attached study pursuant to the terms of the TSCA Section 8(e) Compliance Audit Program (CAP) and the BP America CAP Agreement:

Study Identification

An Acute Inhalation Toxicity Study of Indene in the Rat; Laboratory Study No. 2459-106; Final Report dated July 1, 1987 and Addendum 1 to Final Report dated March 28, 1988.

Identity of Tested Chemical Substance/Mixture and CAS Number (if known)

Chemical: Indene (99+% pure)

CAS Number: 95-13-6

Summary of Results

Groups of rats were exposed in whole body inhalation chambers to a mixture of indene vapor and aerosol at concentrations of 2.99 or 5.22 mg/l for four hours. Following 14 days of post-exposure observations, surviving animals were sacrificed and subjected to a gross postmortem examination.

The median lethal concentration (LC50) for a four-hour exposure to indene is considered to be greater than 5 mg/l based upon the results of this study. Responses noted during or immediately following exposure included: death, prostration, dyspnea, wheezing, salivation, rhinorrhea, languid behavior, squinted eyes, lacrimation, urine stained fur, crust on the eye(s) and hunched appearance. Signs of treatment noted during the two-week post-exposure period included: signs of respiratory distress, hypersensitivity to touch, languid behavior, squinted eyes, urine stained fur, crust on the mouth/nose, and crust on the eyes.

9/9/94

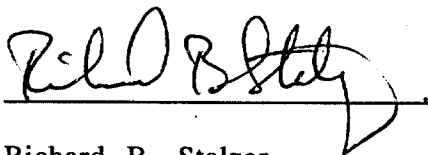
While the types of responses noted in this study during and following indene exposures are commonly observed in response to high concentrations of organic vapors, BP Chemicals notes that a number of the these responses appear in EPA's CAP reporting guidance as suggestive of reportable neurotoxicity.

Previous PMN or 8(e) Submissions by BPA: EPA Document Control Number(s)

None.

BP Chemicals has never manufactured, processed or imported indene for distribution in U. S. commerce, but has occasionally processed indene-containing mixtures for research and development purposes.

Submitted by:



Richard B. Stalzer
Manager, Health, Safety and
Environmental Quality
BP Chemicals, Inc.
216-586-5311

August 25, 1992.

Date



HAZLETON

LABORATORIES AMERICA, INC.
1330 - B PICCARD DRIVE, ROCKVILLE, MARYLAND 20850

SPONSOR: Standard Oil Company

DATE: March 28, 1988

MATERIAL: Indene

SUBJECT: AMENDMENT 1 TO FINAL REPORT
Acute Inhalation Toxicity Study with Indene in the Rat
Project No. 2459-106

Page Nos. 30 and 31 are being submitted as correction pages to delete the designation of "Draft" from the Gross Pathology Incidence Summary table, for incorporation into the subject report dated July 1, 1987.

Study Director:

James B. Terrill 3/28/88
JAMES B. TERRILL, Ph.D., D.A.B.T.
Life Sciences Division



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Sponsor

The Standard Oil Company
200 Public Square
Cleveland, Ohio 44114

FINAL REPORT

Study Title:

Acute Inhalation Toxicity Study
with Indene in the Rat

Data Requirement:

Guideline 81-3

Author:

James B. Terrill, Ph.D., D.A.B.T.

Study Completion Date:

July 1, 1987

Performing Laboratory:

Hazleton Laboratories America, Inc.
9200 Leesburg Turnpike
Vienna, Virginia 22180

Laboratory Project Identification:

HLA Study No. 2459-106



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COMPLIANCE STATEMENT
Acute Inhalation Toxicity Study with Indene in the Rat

To the best of my knowledge this study was conducted in compliance with the Good Laboratory Practice Regulations as set forth in Title 40 of the U.S. Code of Federal Regulations Part 160. Except for possible minor items, there are no significant deviations from the aforementioned regulations which affected the quality or integrity of the study or the interpretation of the results in the report.

Study Director:

James B. Terrill 7-1-87
James B. Terrill, Ph.D., D.A.B.T. Date
Director
Inhalation Toxicology



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CLIENT GLP COMPLIANCE STATEMENT
(To be supplied by the sponsor)

Acute Inhalation Toxicity Study with Indene in the Rat



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OFFICE OF QUALITY ASSURANCE

Project Title: Acute Inhalation Toxicity Study with Indene in the Rat

Project No.: 2459-106

Quality Assurance inspections of the study and review of the final report of the above referenced project were conducted according to the standard operating procedures of the Office of Quality Assurance and according to the general requirements of the Good Laboratory Practice Regulations issued by the Environmental Protection Agency for compliance on or after May 2, 1984. Findings from the inspections and the final report review were reported to management and to the study director on the following dates:

<u>Inspections/Review</u>	<u>Findings Reported</u>	<u>Inspector/Reviewer</u>
Protocol 2/6/87	2/6/87	D. Goldsteen
Inspection 4/29/87	5/5/87	D. Goldsteen
Final Report		
6/11,12,15,16/87	6/22/87	K. Reilly
6/26/87	6/26/87	K. Reilly

Kristine Reilly 7/1/87
Final Report Reviewer Date Released
Office of Quality Assurance



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STUDY IDENTIFICATION
Acute Inhalation Toxicity Study with Indene in the Rat

HLA Study Number	2459-106
Test Material	Indene
Sponsor/Study Monitor	The Standard Oil Company 200 Public Square Cleveland, Ohio 44114
Study Director	James B. Terrill, Ph.D., D.A.B.T. Hazleton Laboratories America, Inc. 1330-B Piccard Drive Rockville, Maryland 20850-4373 (301) 670-9600
Study Timetable	
Initiation Date	April 17, 1987
Termination Date	May 7, 1987

STUDY PERSONNEL
Acute Inhalation Toxicity Study with Indene in the Rat

Study Director:	James B. Terrill, Ph.D., D.A.B.T.
Study Coordinator:	Douglas E. Robinson, M.S.
Laboratory Supervisor:	Preston Burlew, B.A.
Analytical Chemist:	Susan Lewis, Ph.D.



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SUMMARY AND CONCLUSIONS

Groups of male and female Sprague-Dawley rats receiving four-hour inhalation exposures to indene at 2.99 or 5.22 mg/L as a mixture of aerosol and vapor, exhibited increased secretory responses, respiratory distress, signs of irritation of the mucous membranes, urine stained fur and, at the higher exposure level, death. One male and one female rat died on the day of exposure. Body weight values were considered unremarkable. Gross postmortem evaluations revealed a few animals with ocular and respiratory abnormalities. The incidences of these findings were considered insufficient to demonstrate a relation to treatment.

Based on the results of this study, it appears that the median lethal concentration (LC_{50}) for a four-hour exposure to indene is greater than 5 mg/L for Sprague-Dawley rats.

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INTRODUCTION

This study was designed to assess the toxic effects of indene when administered by inhalation. Two groups of Sprague-Dawley rats were exposed to varying concentrations of indene as an aerosol/vapor combination for single four-hour periods. Following 14 days of post-exposure observations, surviving animals were sacrificed and subjected to a gross postmortem examination. The study was conducted by Hazleton Laboratories America, Inc. in its facilities at 1330-B Piccard Drive, Rockville, Maryland 20850. It was designed in accordance with EPA/FIFRA test guidelines, 40 CFR Part 158. The study was conducted in compliance with the EPA/FIFRA Good Laboratory Practice regulations, 40 CFR Part 160.

EXPERIMENTAL DESIGN

Two groups, each of five young male and female Sprague-Dawley rats, were exposed to a combination of indene vapor and aerosol at target concentrations of either 5.0 milligrams per liter (mg/L) or 2.75 mg/L as a single four-hour, whole-body inhalation exposure (Groups 1 and 2, respectively). Upon completion of a 14-day post-exposure observation period, surviving animals were sacrificed and subjected to a gross postmortem examination.

TEST SYSTEM AND METHODS

Test Material

Test Article:	Indene, Gold Label
Purity:	99+%
Supplier:	Aldrich Chemical Co.
Lot No.:	Not Given
Date Received:	January 21, 1987

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Test Material (Continued)

Description:	Clear liquid
Method of Synthesis:	Responsibility of the Sponsor
Composition:	Responsibility of the Sponsor
Expiration Date:	Not Given
Storage Condition:	Room Temperature
Stability:	Responsibility of the sponsor

Test Animals

Species:	Rats						
Strain:	Cr1: CD®(SD)BR						
Number of Animals Placed on Test:	20 (10 males, 10 females)						
Supplier:	Charles River Laboratories, Inc. Raleigh, North Carolina						
Date of Birth:	February 27, 1987 (Males) February 14, 1987 (Females)						
Date Received:	April 7, 1987						
Dates of Exposure:	Group 1: April 17, 1987 Group 2: April 23, 1987						
Weight at Initiation of Exposure (grams):	<table><thead><tr><th></th><th><u>Range</u></th></tr></thead><tbody><tr><td>Males:</td><td>224.5-294.0</td></tr><tr><td>Females:</td><td>202.2-255.3</td></tr></tbody></table>		<u>Range</u>	Males:	224.5-294.0	Females:	202.2-255.3
	<u>Range</u>						
Males:	224.5-294.0						
Females:	202.2-255.3						
Selection and Group Assignment:	The rats were randomly housed upon receipt via computer generated random numbers. Following acclimation to laboratory conditions and pre-test physical examinations, 20 rats were assigned to the study.						
Animal Identification:	Each rat was individually identified with an ear tag and cage card, each bearing its animal number after assignment to the study.						



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Husbandry

During Post-Exposure Period:

Housing:	Animals were housed individually in hanging stainless steel wire mesh cages.
Food:	Purina Certified Laboratory Chow 5002®, <u>ad libitum</u> .
Water:	Tap, <u>ad libitum</u> .
Environmental Conditions:	12-hour light/dark cycle, artificial light. Temperature - 70° to 74°F. Relative Humidity - 38% to 70%*.

During Exposure Period:

Housing:	Individually in stainless steel wire mesh cages.
Food:	None.
Water:	None.

In-Life Observations

During exposure for mortality and gross signs of toxicological or pharmacological effects:

Hourly.

Detailed Physical Examinations:

Prior to and at approximately 30 and 60 minutes after exposure; then performed daily until termination.

Checks for Mortality:

Twice daily.

* The observed relative humidity range exceeded the 40% to 60% range specified in the study protocol. This deviation from protocol was not considered to affect the interpretation of the results.



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Body Weight

Prior to the first exposure and on Test Days 8 and 15 (post-exposure days 7 and 14), or after death for animals dying on study.

Postmortem

Animals found dead or sacrificed at termination of the study:

Gross postmortem examinations were performed on all animals. The external surface, as well as the thoracic, abdominal and cranial cavities and their organs and tissues were subjected to gross examination.

Necropsy:

Number of animals:

20 (10/sex)

Sacrifice method:

Exsanguination while under sodium pentobarbital anesthesia.

Termination dates:

Group 1 - May 1, 1987

Group 2 - May 7, 1987

Tissues preserved:

All gross lesions from terminally sacrificed animals*

* The study protocol specified that all gross lesions would be saved for possible histopathological examination. Gross lesions from two animals that died during the course of the study were not saved. This deviation from protocol was not considered to have affected the conclusions that were drawn from the results of the study.



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CHAMBER OPERATION AND TEST SUBSTANCE ADMINISTRATION

Exposures of the test animals were conducted in a 250 liter (L) stainless steel and glass chamber (see Figures 1 and 2). The chamber was operated in a dynamic mode with total airflow through the chamber of 45 (Group 1) or 46 (Group 2) liters per minute (lpm) as measured by a calibrated orifice plate.

The test material was used as received and was generated as a vapor/aerosol mixture in the breathing zone of the animals. Indene was delivered to one (Group 2) or three (Group 1) DeVilbiss #40 nebulizers (see Figure 3) at a rate of 0.34 mL/minute per nebulizer. HEPA filtered, compressed air was metered through calibrated Dwyer flowmeters and directed into each nebulizer at a rate of 9 lpm. Test material, aerosolized and evaporated by the airstream passing through the nebulizer, exited directly into one of the compound intake connections of the exposure chamber inlet. Within the inlet, the generated indene was diluted with inlet air, and subsequently carried into the exposure chamber.

Following four hours of exposure, the test material generation system was turned off and air passed through the exposure chamber for an additional half-hour to clear residual indene vapor and aerosol. Subsequently, the chamber was opened and the animals were removed.

Atmospheric Sampling

Hourly during each exposure, 10 L (measured by a calibrated flowmeter) of chamber atmosphere were drawn from a sampling port on the side of the chamber through two impingers connected in series. Each impinger contained 15 mL of pesticide grade hexane (Fischer Scientific, H300). Each hexane solution was then assayed for indene content by gas chromatography (see Appendix 1 for details of the analytical procedures). The indene exposure concentration was calculated as the sum of indene (in mg) collected in the two impingers divided by the volume (in L) of test atmosphere sampled.

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One additional sample was drawn during the four-hour exposure from the top of the exposure chamber and assayed for indene to determine the uniformity of the test material within the chamber.

Chamber temperature, relative humidity and airflow were monitored continuously during exposures. Specific readings were recorded half-hourly during each exposure. During the second and fourth hours of each exposure, chamber atmosphere was analyzed for aerosol content and particle size by a TSI Model 3300/3302 Aerodynamic Particle Sizer.

Appropriate components of the generation system with test material were weighed before and after each exposure to determine the quantity of test material consumed. This quantity, when divided by the total airflow through the chamber, yielded the nominal exposure concentration.

Statistics

No statistical analyses were required in the performance of this study, or the interpretation of the results.

RAW DATA AND FINAL REPORT STORAGE

All raw data and the final report are stored in the archives of Hazleton Laboratories America, Inc.

RESULTS AND DISCUSSION

The mean analytical and nominal exposure levels of indene along with the resultant mortality were as follows:

<u>Group</u>	<u>Mean Analytical, mg/L</u>	<u>Nominal, mg/L</u>	<u>#Dead/#Exposed</u>	
			<u>Male</u>	<u>Female</u>
1	5.22 ± 0.448	18.1	1/5	1/5
2	2.99 ± 0.241	6.3	0/5	0/5

The difference between nominal compared to analytical concentration values was attributed to the aerosol in chamber - aerosol will impact on surfaces and large aerosol drops settle rapidly. The comparison of the amount of indene found in the first or upstream tandem impinger (No. A) with the indene level in the second impinger (No. B) indicated good impinger collection efficiency (see Table 1). Comparison of the indene concentration at the normal sample port with the level at the alternate, distribution sample, port suggested good uniformity of the test atmosphere (Table 1).

Particle size distribution and total particulate concentrations are summarized below.

<u>Group</u>	<u>MMAD, microns</u>	<u>Geo. Std. Dev.</u>	<u>Total Particulate, mg/L</u>
1	1.29	3.0	0.0234
	1.42	4.0	0.0301
2	1.46	2.5	0.0129
	1.47	2.6	0.0128

These results indicate the aerosol component of the test atmosphere was respirable in size to the rat, and that most of the indene was present as a vapor.

Chamber temperature and relative humidity values were considered unremarkable.



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One male and one female Group 1 animals were found dead when the exposure chamber was opened. These deaths were considered treatment related. (X)

Squinted eyes, languid behavior, salivation, dyspnea and prostration were exhibited by Group 1 animals during exposure. Upon removal from chamber and at 60 minutes post-exposure, squinted eyes, salivation, languid behavior, prostration, dyspnea, rhinorrhea, crust on the eye(s), eye closed, lacrimation, brown material in the mouth, wheezing, hunched appearance, urine stained fur and death were displayed by the Group 1 animals. Findings in Group 2 animals were generally similar, except no Group 2 animals died.

During the two-week post-exposure period, signs of respiratory distress, sensitivity to touch, languid behavior, squinted eyes, urine stained fur, crust on the mouth/nose and crust on the eyes were found in Group 1 animals. These signs of treatment had generally abated by Test Day 15, and were generally of a lower incidence in Group 2 animals. Other findings were considered sporadic.

Body weight values for both Group 1 and 2 animals were considered unremarkable.

Gross postmortem evaluations revealed failure of the lung to collapse, mottled appearance of the lung, opacity of the eye, raised area on the exterior of the eye and darkened nasal turbinates for Group 1 animals. One Group 2 animal exhibited a darkened lung. These gross postmortem findings occurred in only a few animals and on that basis, their relationship to treatment remains questionable.

Study Director:

Study Coordinator:

James B. Terrill 7/1/87
James B. Terrill, Ph.D.
Diplomate, American Board
of Toxicology

Douglas E. Robinson 7/1/87
Douglas E. Robinson, M.S.

Figure 1
Schematic of the Exposure Chamber and Generation System
(Group 1)

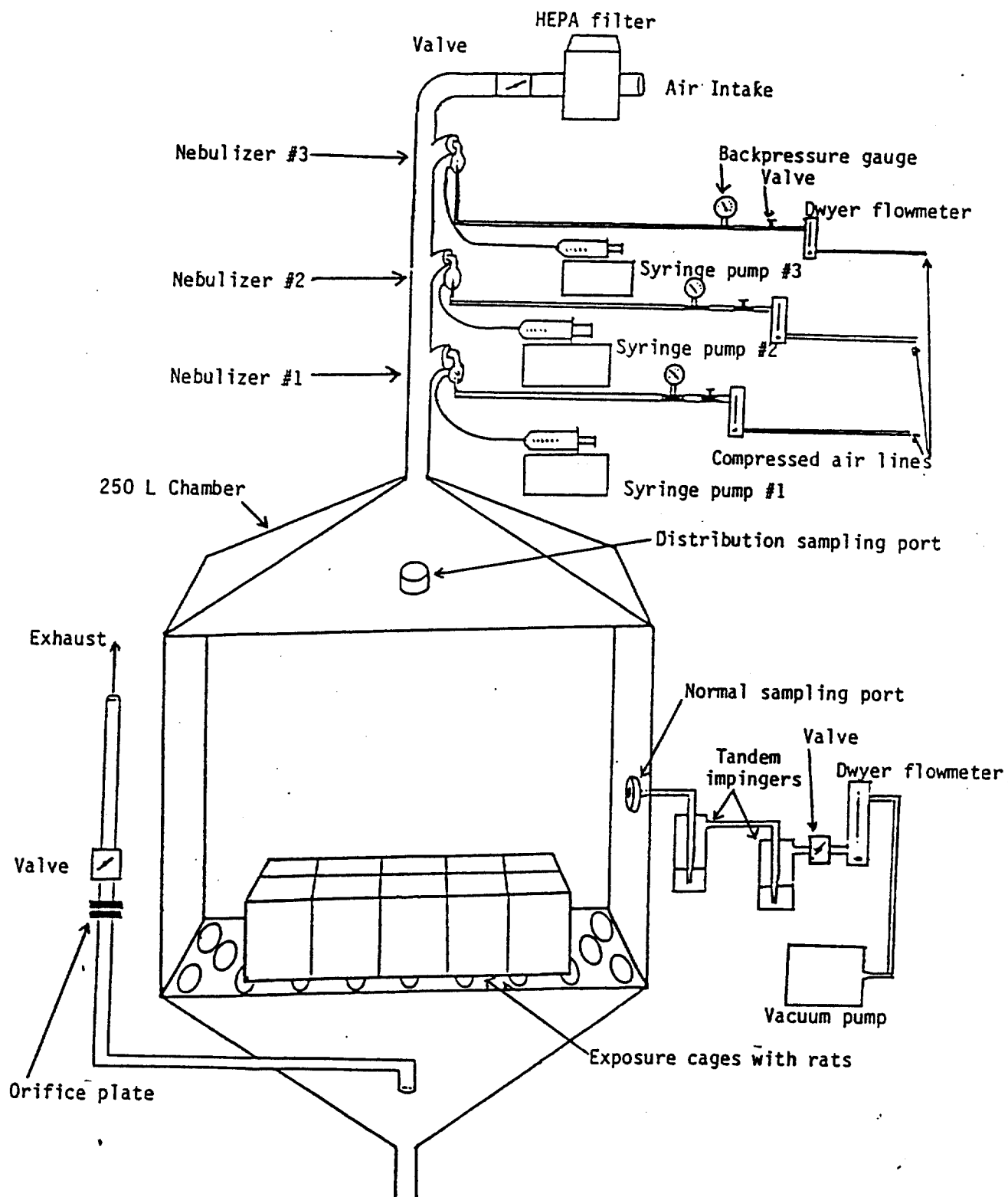
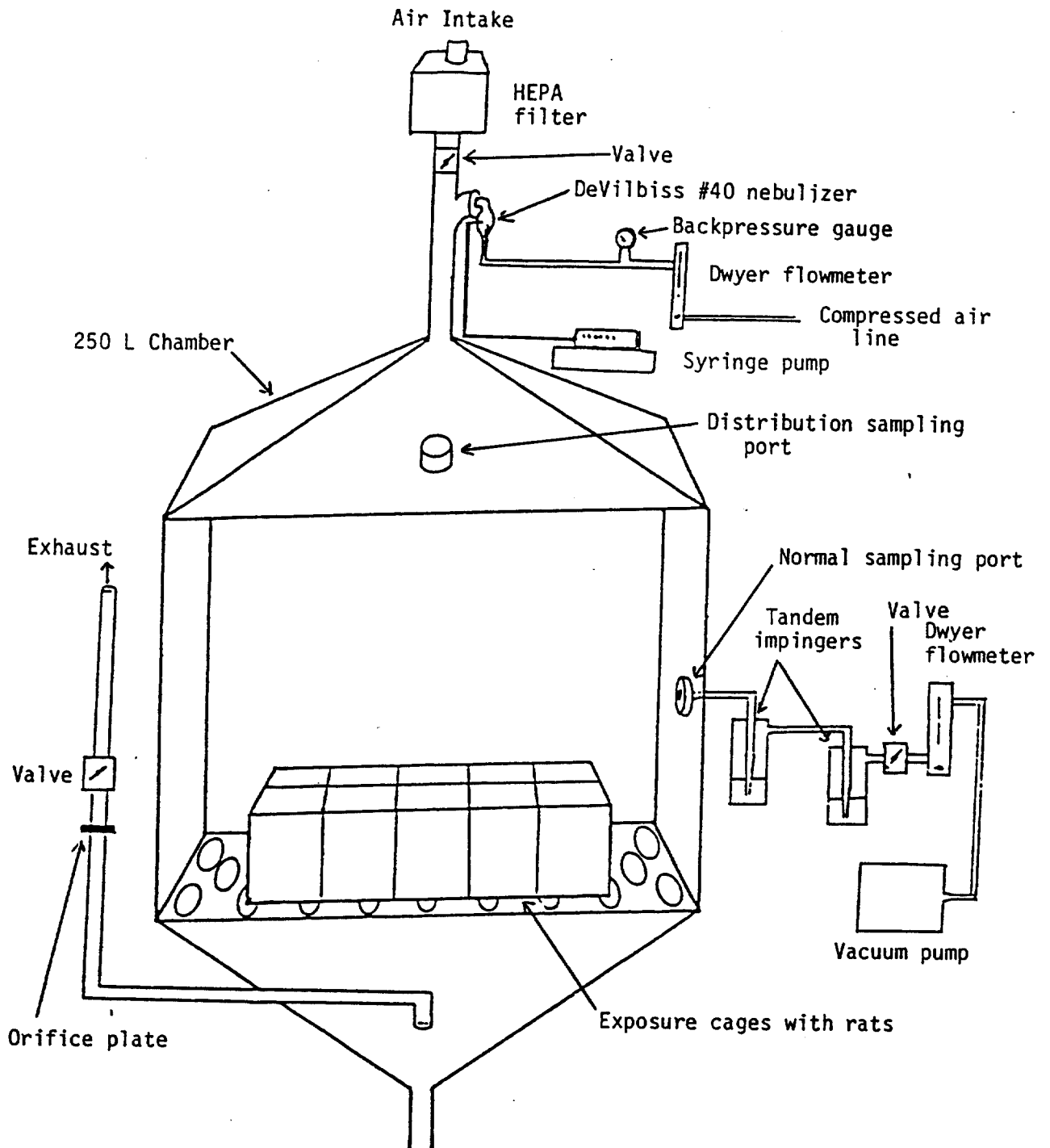
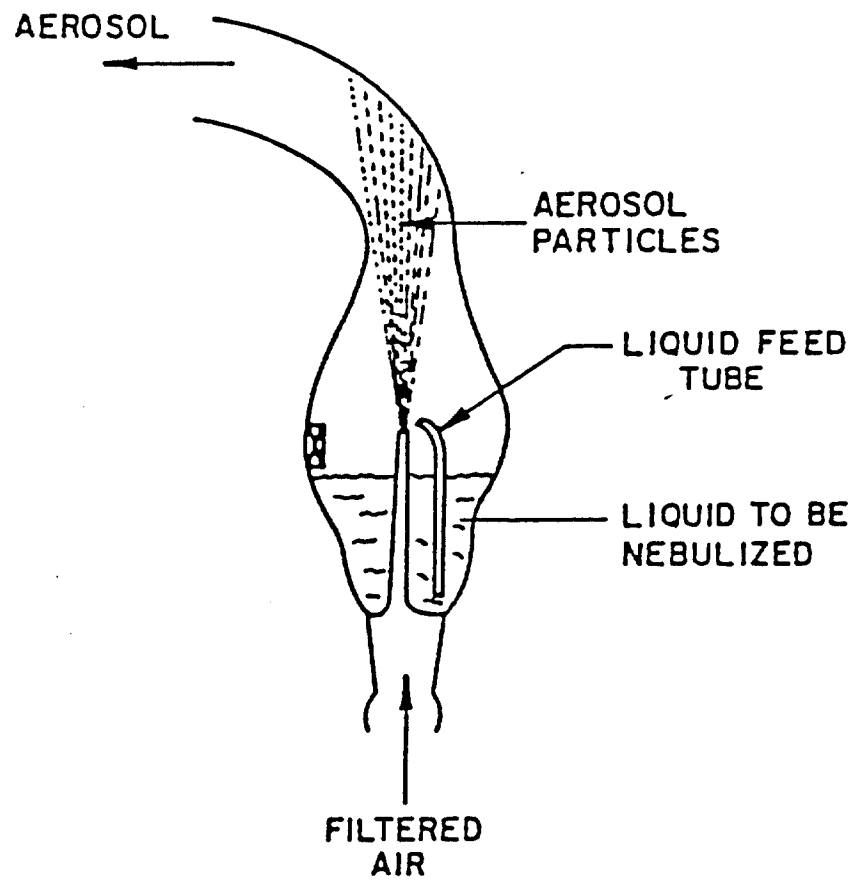


Figure 2
Schematic of the Exposure Chamber and Generation System
(Group 2)



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Figure 3
Schematic of the DeVilbiss #40 Nebulizer



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TABLE 1

EXPOSURE CHAMBER MONITORING RECORD
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT

EXPOSURE GROUP: 1
TEST ARTICLE: Indene
EXPOSURE DATE: 04-17-87

NOMINAL EXPOSURE LEVEL: 18.1 mg/L
EXPOSURE LEVEL: 5.22 ± 0.448 mg/L
EXPOSURE DURATION: 240 Minutes

Time	Minutes of Exposure	Chamber Airflow (lpm)	Temp. (°C)	Relative Humidity (%)	Indene Conc. (mg/L)	Indene Sampled (mg) Impinger A	Impinger B
0815	0	45	20	57	--	--	--
0845	30	45	21	54	5.18 ✓	48.48	3.269
0915	60	45	21	52	--	--	--
0945	90	45	22	50	4.61 ✓	42.75	3.383
1015	120	45	22	49	5.76 ✓	52.39 ^a	5.183 ^a
1045	150	45	22	48	5.97 ✓	55.1	4.576
1115	180	45	22	46	--	--	--
1145	210	45	22	45	5.21 ✓	48.28	3.864
1215	240	45	22	45	--	--	--
1215	240	Generation completed					

MEAN

TWA = 5.22 ± 0.448 mg/L

^a Sampled from the distribution sampling port.

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TABLE 1 (Continued)

EXPOSURE CHAMBER MONITORING RECORD
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RATEXPOSURE GROUP: 2
TEST ARTICLE: Indene
EXPOSURE DATE: 04-23-87NOMINAL EXPOSURE LEVEL: 6.3 mg/L
EXPOSURE LEVEL: 2.99 ± 0.241 mg/L ✓
EXPOSURE DURATION: 240 Minutes

Time	Minutes of Exposure	Chamber Airflow (lpm)	Temp. (°C)	Relative Humidity (%)	Indene Conc. (mg/L)	Indene Sampled (mg) Impinger A	Impinger B
0800	0	46	22	54	--	--	--
0830	30	46	23	60	2.79 ✓	26.61	1.239
0900	60	46	23	59	--	--	--
0930	90	46	24	58	3.01 ✓	28.66	1.480
1000	120	46	24	57	3.48 ✓	32.70 ^a	2.132 ^a
1030	150	46	24	56	3.26 ✓	31.06	1.554
1100	180	46	24	56	--	--	--
1130	210	46	24	56	2.80 ✓	26.65	1.310
1200	240	46	24	57	--	--	--
1200	240	Generation completed					

MEAN

TWA = 2.99 ± 0.241 mg/L ✓^a Sampled from the distribution sampling port.

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TABLE 2
SUMMARY OF CLINICAL OBSERVATIONS
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT

EXPOSURE GROUP: 1
TEST ARTICLE: Indene
EXPOSURE DATE: 04-17-87

EXPOSURE LEVEL: 5.22 ± 0.448 mg/L
EXPOSURE DURATION: 240 Minutes

	<u>PRE-EXPOSURE</u>	<u>HOURS OF EXPOSURE</u>				<u>MINUTES POST-EXPOSURE</u>	
		<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>30</u>	<u>60</u>
<u>NUMBER OF ANIMALS OBSERVED</u>	10	10	10	10	10	10	8
<u>OBSERVATION</u>							
Normal	10	0	0	0	0	0	0
Languid behavior	0	9	10	9	9	0	2
Squinted eye(s)	0	10	10	10	10	5	4
Salivation	0	1	3	4	4	8	7
Prostrate	0	0	0	1	1	5	3
Dyspnea	0	0	0	9	9	4	5
Rhinorrhea	0	0	0	0	0	8	8
Crust on eye(s)	0	0	0	0	0	2	2
Eye closed	0	0	0	0	0	2	2
Lacrimation	0	0	0	0	0	2	1
Brown material in mouth	0	0	0	0	0	1	1
Urine stains	0	0	0	0	0	1	2
Hunched	0	0	0	0	0	0	2
Wheezing	0	0	0	0	0	0	1
Found dead	0	0	0	0	0	2	0

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TABLE 2 (Continued)

SUMMARY OF CLINICAL OBSERVATIONS
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT

EXPOSURE GROUP: 1
TEST ARTICLE: Indene
EXPOSURE DATE: 04-17-87EXPOSURE LEVEL: 5.22 ± 0.448 mg/L
EXPOSURE DURATION: 240 Minutes

NUMBER OF ANIMALS OBSERVED	TEST DAY														
	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>	<u>12</u>	<u>13</u>	<u>14</u>	<u>15</u>	
	8	8	8	8	8	8	8	8	8	8	8	8	8	8	
<u>OBSERVATION</u>															
Normal	0	0	0	0	0	0	0	0	4	4	6	5	6	5	
Wheezing	5	5	5	5	7	3	6	6	0	1	0	0	0	0	
Dyspnea	7	7	7	8	2	4	1	1	0	0	0	0	0	0	
Languid behavior ✓	6	6	6	0	0	0	0	0	0	0	0	0	0	0	
Urine stains ✓	4	4	4	0	0	0	0	0	0	0	0	0	0	0	
Crust on mouth/nose ✓	6	6	6	4	3	3	1	1	1	0	0	0	0	0	
Crust on eyes ✓	2	2	2	0	0	0	0	0	0	0	0	0	0	0	
Epistaxis	1	1	1	0	0	0	0	0	0	0	0	0	0	0	
Sensitive to touch ✓	0	0	0	8	5	0	2	2	2	2	1	2	1	2	
White spot on eye	0	0	0	1	1	1	1	1	1	1	1	1	1	1	
Squinted eye ✓	0	0	0	0	1	1	1	1	1	1	0	0	0	0	
Alopecia	0	0	0	0	0	1	1	1	0	0	1	1	1	1	

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1330 - 8 PICCARD DRIVE, ROCKVILLE, MARYLAND 20850

HLA 2459-106

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TABLE 2 (Continued)

SUMMARY OF CLINICAL OBSERVATIONS
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RATEXPOSURE GROUP: 2
TEST ARTICLE: Indene
EXPOSURE DATE: 04-23-87EXPOSURE LEVEL: 2.99 ± 0.241 mg/L
EXPOSURE DURATION: 240 Minutes

	<u>PRE-EXPOSURE</u>	<u>HOURS OF EXPOSURE</u>				<u>MINUTES POST-EXPOSURE</u>	
		<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>30</u>	<u>60</u>
<u>NUMBER OF ANIMALS OBSERVED</u>	10	10	10	10	10	10	10
<u>OBSERVATION</u>							
Normal	10	0	0	0	0	0	0
Languid behavior	0	10	10	10	10	1	0
Squinted eyes	0	10	10	10	10	1	0
Salivation	0	0	0	0	0	10	9
Prostrate	0	0	0	0	0	1	1
Wheezing	0	0	0	0	0	10	8
Dyspnea	0	0	0	0	0	8	7
Rhinorrhea	0	0	0	0	0	10	10
Polypnea	0	0	0	0	0	1	2
Wet coat	0	0	0	0	0	1	1
Urine stains	0	0	0	0	0	4	8

[illegible]

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TABLE 3

INDIVIDUAL ANIMAL BODY WEIGHTS AND MORTALITY DATA
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RATEXPOSURE GROUP: 1
TEST ARTICLE: Indene
EXPOSURE DATE: 04-17-87EXPOSURE LEVEL: 5.22 ± 0.448 mg/L
EXPOSURE DURATION: 240 Minutes

ANIMAL NUMBER	BODY WEIGHT (grams)			TEST DAY OF DEATH	DISPOSITION
	TEST DAY 1*	8	15		
<u>Males</u>					
7127	255.5	281.8	349.6	15	Terminal Sacrifice
7128	224.5	240.7	295.1	15	Terminal Sacrifice
7129	249.2	--	--	1	Found Dead
7130	233.6	225.0	282.9	15	Terminal Sacrifice
7131	231.9	257.2	323.0	15	Terminal Sacrifice
Mean	238.9✓	251.2	312.7✓		
S.D.	12.90	24.28	29.81		
<u>Females</u>					
7122	229.8	230.7	248.3	15	Terminal Sacrifice
7123	213.4	216.7	239.2	15	Terminal Sacrifice
7124	203.6	--	--	1	Found Dead
7125	202.2	213.8	241.1	15	Terminal Sacrifice
7126	207.8	214.4	230.7	15	Terminal Sacrifice
Mean	211.4	218.9✓	239.8		
S.D.	11.19	7.97	7.24		

* Immediately prior to exposure.

TABLE 3 (Continued)

INDIVIDUAL ANIMAL BODY WEIGHTS AND MORTALITY DATA
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT

EXPOSURE GROUP: 2
TEST ARTICLE: Indene
EXPOSURE DATE: 04-23-87

EXPOSURE LEVEL: 2.99 ± 0.241 mg/L
EXPOSURE DURATION: 240 Minutes

ANIMAL NUMBER	BODY WEIGHT (grams)			TEST DAY OF DEATH	DISPOSITION
	TEST DAY 1*	8	15		
<u>Males</u>					
7142	274.1	284.6	330.6	15	Terminal Sacrifice
7143	294.0	319.6	360.6	15	Terminal Sacrifice
7144	284.6	298.9	348.8	15	Terminal Sacrifice
7145	274.8	303.8	356.5	15	Terminal Sacrifice
7146	277.6	303.4	351.7	15	Terminal Sacrifice
Mean	281.0	302.1	349.6		
S.D.	8.36	12.52	11.56		
<u>Females</u>					
7147	255.3	247.4	265.5	15	Terminal Sacrifice
7148	250.4	256.4	264.5	15	Terminal Sacrifice
7149	244.7	254.9	270.1	15	Terminal Sacrifice
7150	244.7	246.4	270.6	15	Terminal Sacrifice
7151	222.0	233.7	248.2	15	Terminal Sacrifice
Mean	243.4	247.8	263.8		
S.D.	12.77	9.02	9.12		

* Immediately prior to exposure.

Table 4

HAZLETON LABORATORIES AMERICA, INC.
DEPARTMENT OF PATHOLOGY
VIENNA, VIRGINIA

*** PATH/TOX SYSTEM OUTPUT ***
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT.
(LAB GROUP 1, 5.0 MG/L)

PRINTED: 15-MAY-87
PAGE: 1

DRAFT GROSS PATHOLOGY INCIDENCE SUMMARY *DRAFT*

STUDY NUMBER: 2459106

--- NUMBER - OF - A N I M A L S - A F F E C T E D ---

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX: MALE FEMALE

GROUP: -1- -1-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 5 5

** TOP OF LIST **

^COLLECTED/TAKEN (XW) NUMBER EXAMINED: 5 5
NOT REMARKABLE: 0 0

NO SPECIAL REQUIREMENT

5 5

LUNG (LU) NUMBER EXAMINED: 5 5
NOT REMARKABLE: 4 4

FAILURE TO COLLAPSE
MOTTLED

1 0
1 1

EYE (EY) NUMBER EXAMINED: 5 5
NOT REMARKABLE: 3 4

INTERNAL, OPAQUE
EXTERNAL, RAISED AREA

1 1
1 0

NASAL TURBINATE (NT) NUMBER EXAMINED: 5 5
NOT REMARKABLE: 4 4

DARK

1 1

SKIN, OTHER (SS) NUMBER EXAMINED: 5 5
NOT REMARKABLE: 5 5

** END OF LIST **

Table 4 (Continued)

HAZLETON LABORATORIES AMERICA, INC. *** PATH/TOX SYSTEM OUTPUT *** PRINTED: 15-MAY-87
 DEPARTMENT OF PATHOLOGY ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT. PAGE: 1
 VIENNA, VIRGINIA (LAB GROUP 2, 2.75 MG/L)
 DRAFT GROSS PATHOLOGY INCIDENCE SUMMARY *DRAFT* STUDY NUMBER: 2459106

--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---			
TABLE INCLUDES:		SEX: MALE FEMALE	
SEX=ALL;GROUP=ALL;WEEKS=ALL			
DEATH=ALL;SUBSET=ALL			
ORGAN AND KEYWORD(S) OR PHRASE		GROUP: -2- -2-	
		NUMBER: 5 5	
** TOP OF LIST **			
^COLLECTED/TAKEN (XW)		NUMBER EXAMINED: 5 5	
		NOT REMARKABLE: 0 0	
NO SPECIAL REQUIREMENT		5 5	
LUNG (LU)		NUMBER EXAMINED: 5 5	
		NOT REMARKABLE: 4 5	
DARK		1 0	
** END OF LIST **			

CORRECTION PAGE

3/28/88

Table 4

HAZLETON LABORATORIES AMERICA, INC. PRINTED: 15-MAY-87
DEPARTMENT OF PATHOLOGY PAGE: 1
VIENNA, VIRGINIA STUDY NUMBER: 2459106

*** PATH/TOX SYSTEM OUTPUT ***
ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT.
(LAB GROUP 1, 5.0 MG/L)
GROSS PATHOLOGY INCIDENCE SUMMARY

TABLE INCLUDES: SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX: MALE FEMALE

GROUP: -1- -1-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 5 5

.. TOP OF LIST ..

^COLLECTED/TAKEN (XW) NUMBER EXAMINED: 5 5
NOT REMARKABLE: 0 0

NO SPECIAL REQUIREMENT

5 5

LUNG (LU)

NUMBER EXAMINED: 5 5
NOT REMARKABLE: 4 4

FAILURE TO COLLAPSE
MOTTLED

1 0
1 1

EYE (EY)

NUMBER EXAMINED: 5 5
NOT REMARKABLE: 3 4

INTERNAL, OPAQUE
EXTERNAL, RAISED AREA

1 1
1 0

NASAL TURBINATE (NT)

NUMBER EXAMINED: 5 5
NOT REMARKABLE: 4 4

DARK

1 1

SKIN, OTHER (SS)

NUMBER EXAMINED: 5 5
NOT REMARKABLE: 5 5

.. END OF LIST ..

--- NUMBER OF - ANIMALS - AFFECTED ---

Table 4 (Continued)

HAZLETON LABORATORIES AMERICA, INC. *** PATH/TOX SYSTEM OUTPUT *** PRINTED: 15-MAY-87
 DEPARTMENT OF PATHOLOGY ACUTE INHALATION TOXICITY STUDY WITH INDENE IN THE RAT. PAGE: 1
 VIENNA, VIRGINIA (LAB GROUP 2, 2.75 MG/L)
 ----- GROSS PATHOLOGY INCIDENCE SUMMARY STUDY NUMBER: 2459106

--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---			
TABLE INCLUDES:	SEX: MALE	FEMALE	
SEX=ALL;GROUP=ALL;WEEKS=ALL			
DEATH=ALL;SUBSET=ALL			
ORGAN AND KEYWORD(S) OR PHRASE	GROUP: -2-	-2-	
.. TOP OF LIST ..	NUMBER:	5	5
^COLLECTED/TAKEN (XW)	NUMBER EXAMINED:	5	5
NO SPECIAL REQUIREMENT	NOT REMARKABLE:	0	0
LUNG (LU)		5	5
DARK	NUMBER EXAMINED:	5	5
.. END OF LIST ..	NOT REMARKABLE:	4	5
		1	0

CORRECTION PAGE

3/28/88

APPENDIX 1
Analytical Chemistry Method



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HLA 2459-106

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APPENDIX 1

Analytical Chemistry Method

TITLE: Determination of Indene for Inhalation Studies.

STRUCTURE: C_9H_8

ANALYTICAL METHOD NO. 195

DEVELOPED BY: Hazleton Laboratories America, Inc.

1.0 SCOPE:

The method is for the GC analysis of indene from impinger samples used in inhalation studies.

2.0 PRINCIPLE:

The indene is collected in the impinger in hexane and analyzed by gas chromatography using a flame ionization detector (FID).

3.0 EQUIPMENT:

3.1 Gas Chromatograph: Hewlett Packard 5880A equipped with a flame ionization detector and a 5880A terminal or equivalent.

3.2 Glass Column: 2 ft X 2 mm packed with 2% OV101 on WHP.

3.3 Laboratory equipment and glassware.

4.0 REAGENTS:

4.1 Hexane: Baker Resinanalyzed or equivalent.

4.2 Indene standard: supplied by the Standard Oil Company.



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APPENDIX 1 (Continued)

5.0 PROCEDURE:

5.1 Preparation of Standard Solutions

5.1.1 Stock Standard (1 mg/mL)

Weigh 100 mg of indene standard into a 5-10 mL beaker. Transfer to a 100 mL volumetric flask, rinsing the beaker with hexane. Bring to volume with hexane.

5.1.2 Sample Dilution for Standard Curve

- #1 10 ug/mL: 0.50 mL of stock standard to 50 mL with hexane
- #2 20 ug/mL: 1.00 mL of stock standard to 50 mL with hexane
- #3 30 ug/mL: 1.50 mL of stock standard to 50 mL with hexane
- #4 50 ug/mL: 2.50 mL of stock standard to 50 mL with hexane

5.2 Sample Preparation

Dilute or concentrate sample so that a 2 uL injection falls within the range of the standard curve.

5.3 GC Analyses

5.3.1 Instrument Parameters

Instrument: Hewlett Packard 5880A equipped with a flame ionization detector and an HP 5880A terminal or equivalent equipment.

Column: 2 ft X 2 mm glass column packed with 2% OV101 on WHP.

Carrier Gas Flow: Approximately 30 mL/min.



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HLA 2459-106

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APPENDIX 1 (Continued)

Temperature: Oven: 50°C
 Inlet: 225°C
 Detector: 225°C
 Chart Speed: 0.5 cm/min.
 Attenuation: 212
 Quantitation: Height

The above conditions may be changed to optimize the chromatography.

5.3.2 Inject 2 uL of each calibration standard and calibrate the instrument for the standard curve.

5.3.3 Inject 2 uL of each sample.

5.4 Calculations

5.4.1 Calibrate the instrument using the standard curve solutions and the peak height parameter on the integrator.

5.4.2 The nanograms of indene are calculated by the integrator and taken from the printout.

5.4.3 The milligrams of indene are calculated by multiplying the nanograms detected by the calculation factor.

$$\text{Calculation factor} = \frac{\text{Initial volume}}{\text{aliquot}} \times \frac{\text{Final volume}}{\text{uL injected}} \times \frac{1}{1000}$$

6.0 LIST OF FIGURES

Figure 1. Typical Standard Curve.

Figure 2. Typical Chromatograms Standards.

Figure 3. Typical Chromatograms Samples.

STANDARD CURVE
INDENE 4/17/87

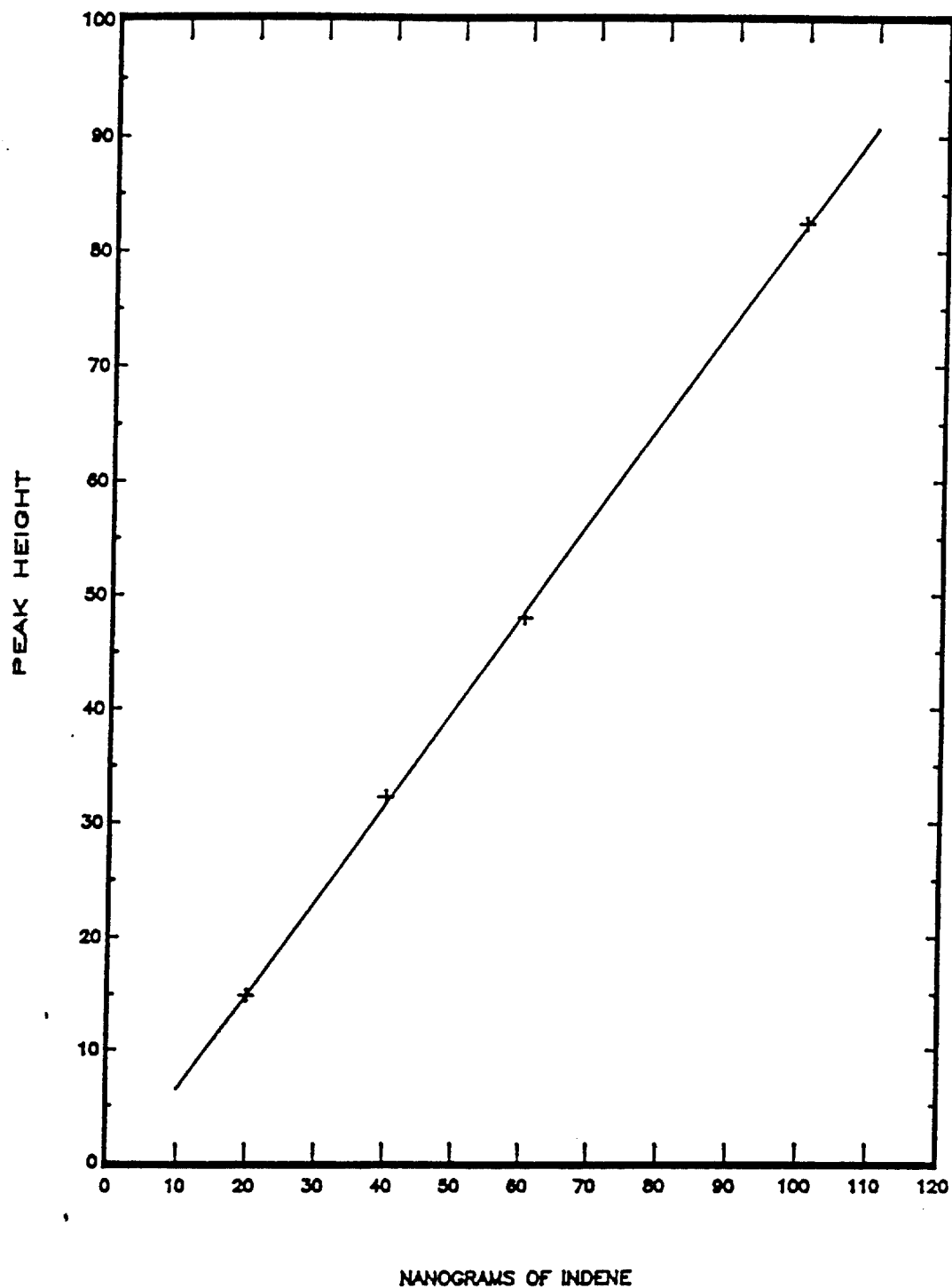
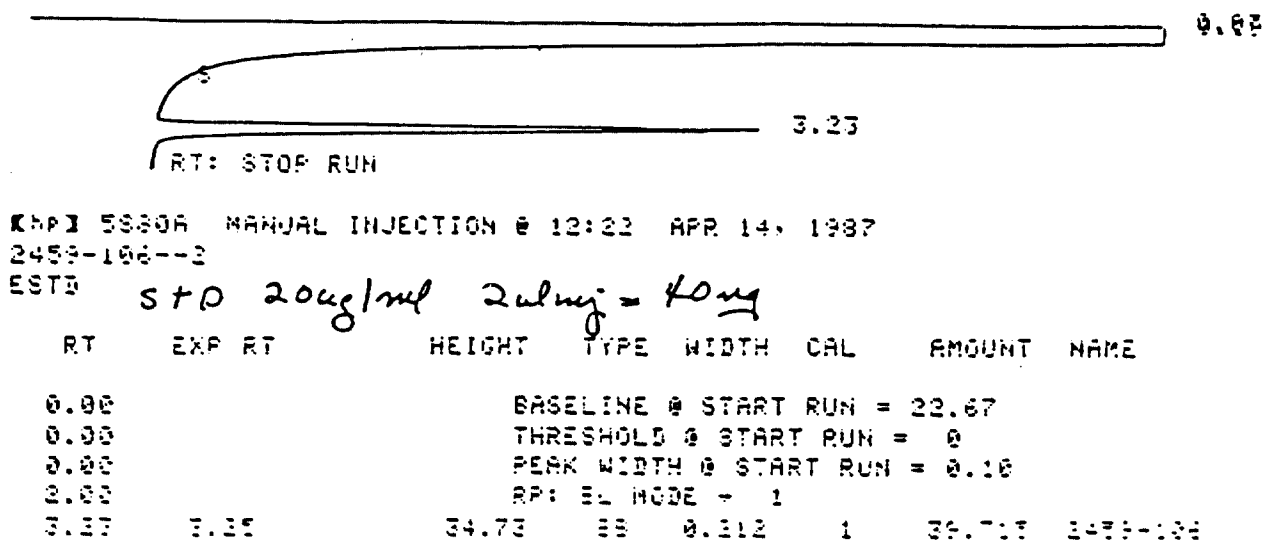


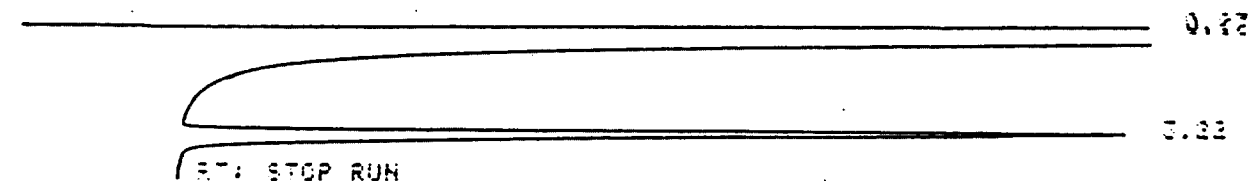
Figure 2



MULTIPLIER = 1

CALIB 1

CAL	RT	NAME	AMT
1	3.23	1459-106	40



MULTIPLIER = 1

CALIB 1

CAL	RT	NAME	AMT
1	3.22	1459-106	60

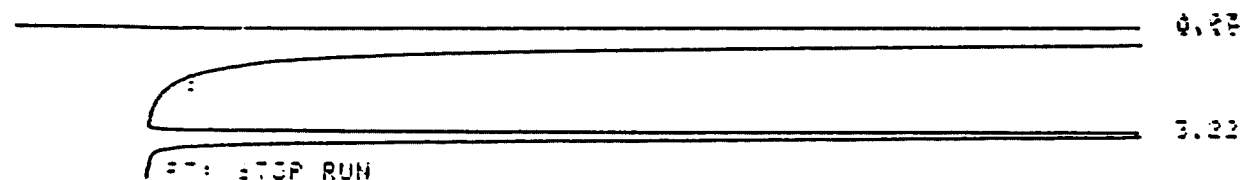


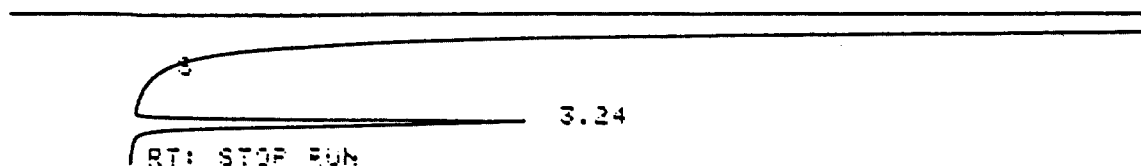
Figure 3

ESTD

RT	EXP RT	HEIGHT	TYPE	WIDTH	CAL	AMOUNT	NAME
0.00							
0.00							
0.00							
0.00							
3.24	3.25	26.67	BB	0.211	1	30.855	2459-106

BASELINE @ START RUN = 22.66
THRESHOLD @ START RUN = 0
PEAK WIDTH @ START RUN = 0.10
RP: BL MODE = 1

MULTIPLIER = 1

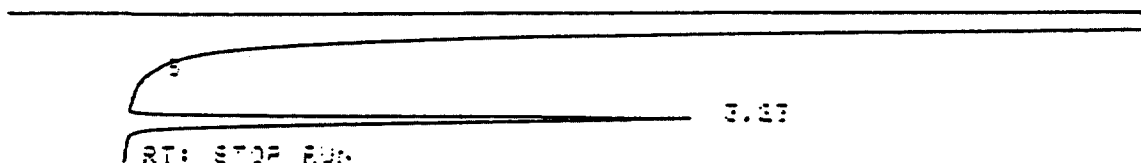


EXP 5880A MANUAL INJECTION @ 15:09 APR 14, 1987
2459-106--2
2170

RT	EXP RT	HEIGHT	TYPE	WIDTH	CAL	AMOUNT	NAME
0.00							
0.00							
0.00							
0.00							
3.24	3.25	21.76	BB	0.212	1	24.982	2459-106

BASELINE @ START RUN = 24.74
THRESHOLD @ START RUN = 0
PEAK WIDTH @ START RUN = 0.10
RP: BL MODE = 1

MULTIPLIER = 1

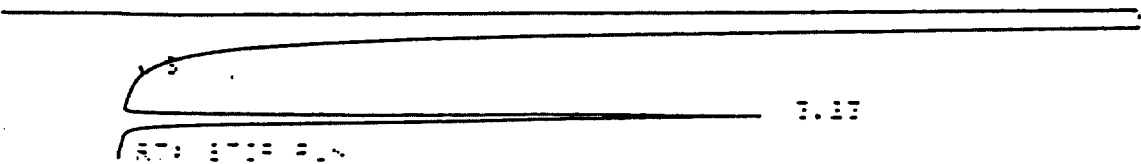


EXP 5880A MANUAL INJECTION @ 15:20 APR 14, 1987
2459-106--2
2171

RT	EXP RT	HEIGHT	TYPE	WIDTH	CAL	AMOUNT	NAME
0.00							
0.00							
0.00							
0.00							
3.17	3.17	21.86	BB	0.213	1	24.979	2459-106

BASELINE @ START RUN = 27.14
THRESHOLD @ START RUN = 0
PEAK WIDTH @ START RUN = 0.10
RP: BL MODE = 1

MULTIPLIER = 1



2ul
11-B
(50ml)
dil
7-25
V

2ul
12-A-2
(50ml)
dil
1-50
V

2ul
12-B-2
(50ml)
dil
7-25
V



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Richard B. Stalzer
Manager, Health, Safety and Environmental Quality
BP Chemicals, Inc.
200 Public Square
Cleveland, Ohio 44114-2375

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

FEB 27 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

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U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12829A



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Triage of 8(e) Submissions

Date sent to triage: FEB 24 1995

NON-CAP

CAP

Submission number: 12829 A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN



Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

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entire document: 0 1 2 pages 1,2 pages 1,2, tab

Notes:

Contractor reviewer : LPS Date: 1/5/95

CECATS/IRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:

Submission # 8ELHQ 0892-12829 SEQ A

TYPE: INT SUPP FLWP

SUBMITTER NAME: BP Chemicals, Inc.

INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL. ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS

0401 NO ACTION REPORTED
0402 STUDIES PLANNED/IN PROGRESS
0403 NOTIFICATION OF WORKER/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 08/28/92 OTS DATE: 08/28/92 CSRAD DATE: 09/09/94

CHEMICAL NAME:

CAS#

95-13-6

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPI/CLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	<u>0242</u> IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	<u>0243</u> CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	<u>0244</u> CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
<u>0212</u> ACUTE TOX. (ANIMAL)	<u>01 02 04</u>	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0239 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY

YES

CAS SR

NO

DETERMINE

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFER:

SPECIES

RAT

TOXICOLOGICAL CONCERN:

LOW

MED

HIGH

USE:

PRODUCTION:

COMMENTS:

-CPSS- 0724951115

0 0 0 0 0 0 0 0 0 0 0

> <ID NUMBER>

8(E)-12829A

> <TOX CONCERN>

L

> <COMMENT>

ACUTE INHALATION TOXICITY IN RATS IS LOW CONCERN BASED ON AN LC50 OF > 5 MG/L FOR A 4-HOUR EXPOSURE. DOSE (MG/L) AND MORTALITY: 5.22 (1/5 M, 1/5 F) AND 2.99 (0/5 M, 0/5 F).

CLINICAL SIGNS INCLUDED

PROSTRATION, DYSPNEA, WHEEZING, SALIVATION, RHINORRHEA, LANGUID BEHAVIOR, SQUINTED EYES, LACRIMATION, URINE STAINED FUR, CRUST ON NOSE/MOUTH AND EYES, HUNCHED POSTURE, SIGNS OF RESPIRATORY DISTRESS, AND HYPERSENSITIVITY TO TOUCH. NECROPSY REVEALED FAILURE OF LUNGS TO COLLAPSE, MOTTLED APPEARANCE OF LUNGS, OPACITY OF THE EYE, RAISED AREA ON THE EXTERIOR OF THE EYE, DARKENED NASAL TURBINATES, AND DARKENED LUNG.

\$\$\$\$